3. Remarks

A. Election/Restriction

Applicants have cancelled claims 72 and 74.

B. Rejection under 35 U.S.C. § 112

The Examiner rejected claims 10, 20, 69, and 102 under 35 U.S.C. § 112 as being indefinite. In response, Applicants have requested amendment of these claims to remove "and/or", modify the dependency, and provide antecedent bases. Applicants have also requested an amendment of claim 70 to correct dependency in a manner similar to the correction in Claim 69.

C. Double Patenting

Claim 63 has been cancelled.

D. Rejection of Claims under 35 U.S.C. § 102

The Examiner has rejected claims 1, 3, 61 and 102 - 103 under 35 U.S.C. § 102 as being anticipated over **Koch** (U.S. Pat. No. 4,465,067). The Examiner states that **Koch** discloses a method for delivering a therapeutic gas, oxygen, to a person having a nasal/oral mucus membrane, which comprises generating a flow of the gas and infusing the nasal or oral mucus membrane, wherein the person refrains from inhaling. The Examiner states that "by dint of anatomy" both the nasal and oral cavities will be infused when gas is delivered to one.

Applicants note that Claim 1 has been amended to clarify that the person refrains from inhaling *the therapeutic gas*.

Koch discloses a device for oxygen insufflation. Significantly, **Koch** specifically states that the device's purpose is to improve the patient's *breathing*. (See, e.g., Col. 1, Line 56; Col 2, Lines 43 - 46). Nowhere in **Koch** is there a suggestion that the while the oxygen is "blown into .. one nostril" (Col. 2, Line 17) the patient should refrain from inhaling the therapeutic gas, as is required in Claims 1 and 103, or inhibit the passage of the therapeutic gas into the trachea and lung by limiting inhalation, as is required by Claims 61 and 102.

The Examiner's statement that "the gas is delivered to insufflate the oronasal cavity, hence delivery is not primarily for breathing but insufflation, if the user where to breath the gas could not insufflate the nasal cavity [sic]," is directly contradicted by **Koch**: "The invention is direct to oxygen insufflation spectacles ... which facilitate the patient's breathing by supplying the respiratory ducts with a mixture enriched in oxygen." (Col 1, Lines 54 - 58); "[T]he oxygen is blown in only through one nostril which, otherwise, is completely closed. The patient can use the other nostril for unobstructed exhaling, while at the same time further oxygen is blown into a part of the respiratory ducts and is instantly available for, and ensures, a high oxygen concentration." Further, Applicants note that insufflation has nothing to do with breathing: the current on-line version of the Merriam-Webster Dictionary defines "insufflate" as "the act of blowing something (as a gas, powder, or vapor) into a body cavity." This is consistent with **Koch**'s anticipation of insufflating or blowing oxygen into the nose throughout the entire, normal breathing cycle.

As noted above, **Koch** does state that one advantage of the device is that while oxygen is blown into one nostril, which is otherwise closed, the patient can exhale through the other nostril. The result is that "further oxygen is blown into a part of the respiratory ducts and is instantly available for, and ensures a high oxygen concentration." (Col 2, Lines 15 - 22). However, continuing a flow of oxygen while the patient exhales during a normal cycle of inhalation and exhalation, which **Koch** teaches, is not the same as having the patient *refrain* from inhalation of the gas as Claims 1 and 103 require. **Koch** never states or suggests that the patient not inhale the gas; as the reference clearly shows, the gas is

expected to be inhaled. Further, with respect to Claims 61 and 102, **Koch** actually teaches against inhibiting the passage of the therapeutic gas into the trachea and lung -- the whole purpose of the **Koch** device is to supply the respiratory ducts with a gas mixture enriched in oxygen. (Col 1, Lines 55 - 57; Col 2, Lines 15 - 18).

Since **Koch** does not show the invention as claimed, Applicants respectfully suggest that the rejection under 35 U.S.C. § 102 is not appropriate. Claims 1, 61, 102 - 103 and their dependent claims are allowable.

E. Rejection of Claims under 35 U.S.C. § 103

Claims 6-9

The Examiner has rejected claims 6-9 as being unpatentable over **Koch**. The Examiner states that **Koch** discloses the claimed invention except for the flow rates, time range of flow, and repetitive steps.

As noted above in the discussion regarding Rejection of Claim 1, from which each of these claims depend, under 35 U.S.C. § 102, **Koch** does not show the invention as claimed. Therefore, on this ground alone, each of these claims is allowable.

Moreover, with respect to the feature of a low flow rate of between .05 cc/sec and 20 cc/sec in Claim 6, as the Examiner notes, **Koch** does not give any particular flow rate. However, such a flow rate cannot be merely a "design choice" as the Examiner suggests. As noted above, the stated purpose of the **Koch** device is to provide a "high oxygen concentration" in the mixture of air and oxygen created as the patient breathes. The average tidal value (air inhaled during a normal breath) for the human lung is about 0.5 liters and the average adult inhalation is completed in less than 2 seconds (based on 15 to 20 breaths per minute). Thus, if the **Koch** device used even the maximum flow rate claimed, only 40 cc of pure oxygen would be available to the patient per breath. Thus, the resulting mixture would be at most 27% oxygen, in comparison to 21% oxygen in air.

Applicants therefore suggest that there would be no motivation to have such a low flow rate in the **Koch** device.

With regard to time range of the flow, the **Koch** device is specifically designed for long term wear and use. One of the objectives of the device is to avoid the "disfiguring impression" that oxygen spectacles produce for long-term use (Col 1, Lines 45 - 47). Obviously, **Koch** anticipates application of a continous flow of oxygen for significantly longer 100 seconds. Thus, there is no motivation provided in **Koch** for a "design choice" of a gas for between 1 and 100 seconds as is required in Claim 7, nor repeated applications of such a flow as is required in Claims 8 and 9.

Claims 5 and 75

The Examiner has rejected Claims 5 and 75 as being unpatentable over **Koch** as applied to Claim 3, and further in view of **Zapol** (U.S. Pat. No. 5,485,827). The Examiner again states that **Koch** discloses the claimed invention. As stated above with respect to Claim 1 from which each of Claims 5 and 75 depend, **Koch** does not show the invention as claimed. Therefore, each of these claims is allowable.

Claims 4, 62-63 and 65-68

The Examiner has rejected Claims 4, 62-63 and 65-68 as being unpatentable over **Koch**, and further in view of **Fukunaga** (U.S. Pat. No. 5,983,891). The Examiner states that with regard to Claim 4 **Koch** discloses the claimed invention except for the use of carbon dioxide, which is shown in **Fukunaga**. The Examiner states that with regards to Claim 4, **Fukunaga** teaches the use of carbon dioxide, and that a motivation to combine is to provide oxygenation of the user. The Examiner further states that the selection of a gas is a matter of mere design choice and would be obvious to one of ordinary skill in the art.

In addition, the Examiner states that with respect to Claim 62, which requires that the carbon dioxide be in a carrier gas, the remaining components of the ventilatory gasses being delivered to the user function as a carrier gas in **Koch** and **Fukunaga**. Finally,

with respect to Claims 65-68, which provide for particular the Examiner reasserts his argument that flow rates, time ranges and repetitive steps are "design choices."

Applicants note that Claim 63 has been cancelled.

For the reasons set forth above with respect to Claim 1 from which Claims 62, and 65-68 depend, Applicants again assert that **Koch** does not show the invention as claimed. Therefore, each of the claims is allowable.

With regard to Claim 4, **Fukunaga** teaches an artificial ventilation system which includes a "dead space" to allow for mixture of inspiratory gases and expiratory gases, thus allowing the patient to "rebreathe" a controlled amount of expired carbon dioxide. However, while **Fukunaga** does describe the use of carbon dioxide, it, like **Koch**, describes its use solely in the context of inhalation, and thus, as noted above, does not teach or suggest the claimed invention.

Moreover, the teaching of **Fukunaga** with respect to carbon dioxide is not logically combinable with the **Koch** device. While both of the devices relate to the "respiratory arts," the context of use is quite different. The **Fukunaga** device is intended for artificial ventilation; in other words, all of the gases the patient inhales come through the ventilation device such that insuring sufficient carbon dioxide in the gases provided to the patient is essential to maintain oxygenation of the patient; having the correct balance of gases, and monitoring their effect, is critical. In contrast, the **Koch** device is intended for use by a patient who is breathing on his own with access to ambient air: during use of the **Koch** device the patient has access to carbon dioxide through the unblocked nostril. There is thus no need, and no motivation, to provide a flow of carbon dioxide to the patient. In fact, one of the major goals of the **Koch** device is increasing the oxygen enrichment available to the patient (Col. 1, Lines 48 – 50; Col. 2, Lines 18 – 22), and adding carbon dioxide to the flow of gas in **Koch** would tend to work against the stated goal.

Thus, for the reasons stated, a person of ordinary skill in the art would not be motivated to add carbon dioxide as taught in **Fukunaga** to the flow of the **Koch** device. Therefore, Claim 4 and its dependent claims 62 and 65-68 are allowable.

In addition, with respect to Claims 65 – 68, Applicants respectfully refer to their earlier arguments in connection with Claims 6-9 regarding "design choice." For the same reasons, each of claims 65-68 is also allowable.

Claims 10-12, 14-15

The Examiner has rejected Claims 10-12 and 14-15 as being unpatentable over **Koch**, and further in view of **Zimmerman** (U.S. Pat. No. 4,273,124). The Examiner states that **Koch** teaches the claimed device but does not explicitly teach allowing the flow of gas to exit by the other nostril and/or mouth. The Examiner further states that **Zimmerman** teaches this feature. He also states that a person of ordinary skill would have been motivated to combined the references so as to optimize the flow of gas and prevent the back pressure buildup in the oro-nasal/sinus cavity.

For the reasons set forth above with respect to Claim 1 from which Claims 10-12 and 14-15 depend, Applicants again assert that **Koch** does not show the invention as claimed. Therefore, each of these claims is allowable.

Further, with respect to Claims 14-15, the Examiner states that "suggested device is fully capable of adjustment of the flow rate to the patient's perceived comfort level" thus suggesting the claimed feature of adjusting the flow rate based upon the patient's comfort level. However, neither **Koch** nor **Zimmerman** suggests any kind of adjustment in flow rate – based on the patient's comfort level or otherwise. In fact, **Zimmerman** states "[t]herapeutic gas only is being inhaled into the nostril with the bulbous member at a *set flowrate* while any additional gas to supply the patient's total inhalation flow rate must enter the other nostril open to ambient air." (Col. 4, Lines 5- 9. Emphasis added.) This suggests that no adjustment to the flow rate is contemplated. Further, in both **Koch** and

Further, with respect to Claim 16 as amended, while **Duncan** does suggest that the device could be used for other gases or drugs (Col. 3, Lines 73-75), **Duncan** provides no indication of the particular gases that could be used, nor any motivation to administer these gases with a low flow rate given the clear intended use of the **Duncan** device as an inhaler.

Claim 20, which depends from Claim 16, is allowable based upon the allowability of its parent claim. Also, Claim 20 includes the further limitation that the treatment gas be a therapeutic gas and a gas selected from among oxygen, nitrogen, and halogenated hydrocarbons. **Duncan** does not teach or suggest this particular combination.
Claim 69 - 70 have been amended to depend from Claim 18 and are also allowable as depending from claims 16 and 18. As now written they require that the gas flow comprise carbon dioxide in a carrier gas. In addition, in Claim 69 the carrier gas must be inert, and in Claim 70 the carrier gas must be biologically active. The Examiner has stated that the choice of the gases, in particular the choice of a biologically active versus an inert carrier gas is a mere design choice. However, the specific limitation that the gas flow be carbon dioxide with an inert or biologically active carrier gas is not taught or suggested.

Claim 21 is allowable on based on the allowability of Claim 16.

With respect to Claim 22, the Examiner states that the device disclosed by **Duncan** is capable of sealing against a patient's mouth, and further states that nasal and oral patient airway interfaces are interchangeable mechanical equivalents in the art. However, although it might be possible to use the **Duncan** device in the mouth, the device is specifically designed for use in the nostrils, and nothing in the reference suggests any other use.

With respect to Claims 24 - 27, the Examiner essentially repeats his arguments regarding flow rates and time ranges for delivery made in connection with Claims 6-9. As was the

Zimmerman the devices are positioned on the patient so as not to be easily removable or otherwise designed to be capable of effecting an adjustment to the flow rate.

Thus the references, even in combination, do not suggest an adjustment of the flow of gas, and Claims 14 – 15 are therefore allowable.

Claims 16, 20 - 22, 24 - 27, 69-70

The Examiner has rejected Claim 16 over **Duncan** (U.S. Pat. No. 2,860,634). The Examiner states that **Duncan** substantially discloses the claimed invention to include the release of a flow of treatment gas from a hand-held dispenser, but does not disclose the specific flow range of 0.5 cc/sec to 20 cc/sec. The Examiner repeats his argument made in connection with Claims 6-9 regarding flow rate as a "design choice."

Claim 16 has been amended to delete oxygen from the list of gases. Claim 106 has been added, which is essentially the same as Claim 16 but which claims only oxygen as the therapeutic gas. Applicants point out that **Duncan** does not teach the use of gas other than oxygen and that Claim 16 is allowable on this basis alone.

In addition, with respect to both claims 16 and newly added claim 106, applicants respectfully point out that **Duncan**, like **Koch**, teaches a device that is intended for use as an inhaler. **Duncan** includes a nose piece that fits into both nostrils, thus suggesting that the user will obtain all of the gas needed for at least one breath from the device. As discussed above with respect to Claims 6-9, the average tidal value (air inhaled during a normal breath) for the human lung is about 0.5 liters and the average adult inhalation is completed in less than 2 seconds (based on 15 to 20 breaths per minute). Thus, although **Duncan** does not disclose a specific flow rate, if the device is to be used for inhalation, logically the flow would generally have to be on the order of .25 liters/sec or about 250 cc/sec – significantly more than the low flow rate claimed. This is further supported by the fact that **Duncan** indicates that each bottle will be sufficient for only "several" treatments (Col. 3, Lines 71-72). There is thus no motivation provided in **Duncan** to have a low flow rate, given the intended use of the device for inhalation.

case with the **Koch** reference, the **Duncan** device is simply not designed for the claimed flow rate or time ranges. As with **Koch**, the **Duncan** device is designed for inhalation. Thus, for the reasons set forth with respect to **Koch** including the well-known facts regarding human respiration, the flow rate is neither taught nor suggested. In addition, it is clear that the **Duncan** device can only be used for "several" applications -- or inhalations. Thus, given the flow necessary to allow inhalation as the **Duncan** device intends, it is rather unlikely -- given a handheld device -- that the required flow could be maintained for 100 seconds. Finally, with respect to Claim 27, there is no provision in **Duncan** for any adjustment of the flow rate. (See, for example, Col. 3, Lines 49 - 34.) Thus, the adjustment limitation of Claim 27 cannot be taught or suggested by **Duncan**.

Claim 76

The Examiner has rejected Claim 76 as being unpatentable over **Duncan** as applied to Claim 16 and further in view of **Zapol** (U.S. Pat. No. 5,485,827). As a dependent claim, Claim 76 is allowable for the reasons set forth in the discussion of Claim 16. It should be noted that **Zapol** specifically teaches inhalation. The low flow rate is neither taught nor suggested by the reference.

Claims 17-18

Although not specifically discussed in the Office action, applicants respectfully suggest that, for the reasons set forth above in the discussion of Claim 16, the references to do not teach or suggest the combination of the features of the stated low flow rate with a flow of CO_2 or a flow of CO_2 in a carrier gas, as set forth in Claims 17 and 18. Both claims are therefore allowable.

Claim 92

Applicants acknowledge the Examiner's statement regarding the allowability of Claim 92 if rewritten in independent form.

4. Conclusion

For the reasons set forth above, applicants respectfully request reconsideration and allowance of all claims.

Respectfully submitted,

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